19. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 356.

20. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 569.

21. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 619.

REMARKS

Of the 9 original claims, claims 1 and 2 have been amended, claims 3-9 have been withdrawn from consideration and claims 10 to 21 have been added. Support for these amendments may be found in the original claims and throughout the specification, *e.g.*, page 44, lines 11-19. No new matter is introduced by these amendments.

With this response, claims 1, 2 and 10-21 are now pending. Applicants do not believe that any fees are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Arnold & Porter Account No. 01-2510.

I. Restriction Requirement

The Examiner acknowledges the election of group I, claims 1 and 2, in Paper No. 7 with traverse. However, the Examiner rejects the grounds for traverse and makes the restriction requirement final. The Examiner also notes the election of SEQ ID NOs: 1, 4, 14, 27, 225, 298,

311, 356, 569, and 619 in Paper No. 7 with traverse. While Applicants disagree with the Examiner, to facilitate prosecution Applicants have amended the claims to recite the elected sequences.

II. Priority

The Examiner challenges Applicants' claim for priority under 35 U.S.C. §119(e) to U.S. Provisional Application No. 60/083,390, filed April 29, 1998, because the CRF filed in the provisional application is allegedly defective, and therefore it is allegedly not possible to determine whether any given sequence was disclosed in the priority application. Applicants respectfully disagree. A provisional application is not required to comply with the formal sequence listing guidelines and is not required to include a CRF. 37 C.F.R. § 1.821(g).

Applicants have made a proper claim of priority to the provisional application. A sequence listing that identifies each sequence by a unique "SEQ ID NO" was filed in the Applicants' provisional application (in paper and computer readable form). Regardless of the condition of the CRF, a particular sequence may be readily located by reference to the paper copy of the sequence listing in the provisional application. Applicants respectfully submit that there is no basis for denying Applicants' priority claim.

III. Specification

The Examiner notes the incorporation of embedded hyperlinks on pages 9 and 56 of the specification. According to MPEP §608.01, embedded hyperlinks and browser executable code are not permitted. The specification has been amended to remove the phrase "http://." No new matter has been added by this amendment. Applicants request that the objection to the

specification be withdrawn.

IV. Rejection under 35 U.S.C. §101

Claims 1 and 2 were rejected under 35 U.S.C. §101, because the claimed invention is allegedly not supported by either a specific or substantial utility or well-established utility as outlined in the Revised Interim Utility and Written Description Guidelines ("Interim Guidelines"). The Examiner acknowledges that "[t]he specification states that the nucleic acid compounds may be useful as probes for assisting in the isolation of full-length cDNAs or genes which would be used to make protein and optimally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as Northern blot analysis, molecular weight markers, chromosomal markers, and for numerous other generic genetic engineering usages. Similarly, protein may be used for detection of expression, antibody production, Western blots, etc." Office Action dated December 20, 2000, at page 5. However, the Examiner contends that none of these utilities constitute a "specific" utility as defined in the Interim Guidelines. In addition, the Examiner contends that the invention does not constitute a specific and substantial utility claiming that "[i]dentifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use" and that the "asserted utilities [are] generic in nature and applicable to a myriad of such compounds." Office Action dated December 20, 2000, at page 6.

Applicants traverse this rejection. The Examiner's application of these Interim Guidelines ignores the presently disclosed specific, credible, and well-established utilities and contravenes well-established doctrines of utility developed in the courts.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. For example, the invention is useful for determining the presence and/or identity of polymorphisms, measuring the level of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements to such molecules, screening maize and soybean cDNA or genomic libraries, obtaining nucleic acid homologues, detecting and characterizing gene expression, *etc.* (*see e.g.,* Specification, beginning at page 63, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. §101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. §101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather, the Examiner attempts to undermine the existing utilities by stating the uses "...are non-specific uses that are applicable to

nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acid(s) being claimed. Office Action dated December 20, 2000, at page 5. Further, the Examiner contends that "the research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility...(because)...identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a 'real world' context of use." Office Action dated December 20, 2000, at page 6. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law - there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933)). Thus, it must be the case that an utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used

in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. §101.

Surprisingly, the Examiner notes that the credibility of the presently asserted utilities has not been assessed. Office Action dated December 20, 2000, at page 6. This is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), (quoting *Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985)). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...").

Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

The Examiner notes that "[A]pplicant(s) have listed a number of sequences which are known in the prior are and which has a high percentage sequence similarity to a claimed sequence." Office Action dated December 20, 2000 at page 6. The Examiner contends that "absent factual evidence, a percentage sequence similarity of less than 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule." *Id.* Applicants disagree with this contention. However, the claimed molecules have other utilities such as determining the presence and/or identity of polymorphisms, measuring the level of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements to such molecules, screening maize and soybean cDNA or genomic libraries, obtaining nucleic acid homologues, detecting and characterizing gene expression, *etc.* (*see e.g.,* Specification, beginning at page 63, under heading "Uses of the Agents of the Invention").

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1 and 2 under 35 U.S.C. §101 is incorrect and should be withdrawn.

V. Rejection under 35 U.S.C. §112, 1st Paragraph: Written Description

Claims 1-2 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in a manner that reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time of filing. In particular, the Examiner contends that the specification provides insufficient written description to support the genus encompassed by the claims. Applicants respectfully disagree.

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-Mar-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), (quoting *In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981)). Thus, simply because the claimed nucleic acid

sequences may also include full length genes, DNA constructs that encode fusion proteins, and cDNAs does not require that Applicants describe each and every one of these molecules.

The Examiner quotes *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 and claims that "[t]he species specifically disclosed are not representative of the genus because the genus is highly variant." Office Action dated December 20, 2000 at page 9.

Applicants assert that the genus of sequences encompassed by the presently amended claims are supported by Applicants' disclosure. First, Applicants have recited a representative number of sequences defined by nucleotide sequence, which fall "within the scope of the genus," i.e., SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, and 619. Second, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NOs: 45, 254, 552, 1296, 1701, 1982, 2001, 2525, and 3500. Moreover, closely related nucleic acid molecules falling within the scope of the present claims are readily recognizable – they either hybridize under the presently claimed conditions to SEQ ID NOs: 45, 254, 552, 1296, 1701, 1982, 2001, 2525, or 3500 (or any complements thereof), or they do not. The fact that the nucleic acid molecules may comprise additional sequences, *etc.* is beside the point. Such additional species are readily envisioned by one of ordinary skill in the art and disclosed throughout the present specification. Third, not only have Applicants disclosed structural features, but they have also defined the polynucleotide in functional terms, e.g., a "nucleic acid molecule that encodes a maize or soybean phosphogluconate pathway enzyme" Claim 1.

Consequently, the present case is clearly different from *Eli Lilly*. The present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. 119 F.3d 1559, 43 U.S.P.Q.2d 1398, 1568-69 (Fed. Cir. 1997) ("a cDNA is not defined or

described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.").

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, 1st paragraph be withdrawn.

VI. Rejections under 35 U.S.C. §112, 2nd Paragraph

Claims 1 and 2 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner contends that the limits of the term "fragment thereof" are unclear. Applicants disagree. The phrase "fragment thereof" is defined in the specification at, for example page 42, lines 5-8. Therefore, the metes and bounds of the claims are clear. Nevertheless, to facilitate prosecution, the claims have been amended and no longer recite this limitation.

In addition, the Examiner contends that the term "putative enzyme" is confusing as to what it intends to encompass. Applicants disagree. Table A of the specification sets forth the definition of a putative enzyme. However, to facilitate prosecution, Applicants have amended the claims.

In view of the above, Applicants respectfully request that rejections under 35 U.S.C. §112, 2nd paragraph, be withdrawn.

VI. Double Patenting

Claims 1 and 2 were provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims drawn to polynucleotides of copending Application

Nos. 09/304,517 and 09/262,979. Applicants respectfully request that as neither of the co-pending applications have yet passed to issue, the rejection be stayed.

VII. Rejection under 35 U.S.C. §102

Claim 1 was rejected under 35 U.S.C. §102(a) as allegedly being anticipated by AB007907, and under 35 U.S.C. §102(b) as allegedly being anticipated by AF037030. Applicants disagree with the rejections.

The references do not anticipate the present claims. For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988). Applicants contend that this reference does not teach every element of the presently claimed invention. The presently amended claim recites nucleic acid molecules that hybridize to a nucleic acid molecule selected from the recited Markush group under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C.

Whatever else AB007907 and AF037030 may disclose or suggest, they do not disclose or suggest a nucleic acid molecule that hybridizes to a nucleic acid molecule selected from the Markush group under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C. The Examiner has also asserted that the cited references have some homology to SEQ ID NO: 27 and SEQ ID NO: 14, but has not disclosed the extent of the homology. This assertion is insufficient to establish an assertion that the cited references anticipate the present claims.

Claim 1 was also rejected under 35 U.S.C. §102(b) as allegedly being anticipated by

Katsurada (Tezukayama-Gakuin Junior College Annual Report of Scientific Studies, 1997, No. 45. Pages 58-73 [Abstract only]), Katsurada (Tezukayama-Gakuin Junior College Annual Report of Scientific Studies, 1996, No. 44. Pages 89-104 [Abstract only]), and Lal *et al.* (Lal *et al.* Plant Physiology (1995) Vol 108, No 3, Pg 1295-1296). The Examiner contends that each of these three references anticipates claim 1. Applicants respectfully disagree.

As stated above, for a prior art reference to anticipate in terms of 35 U.S.C. §102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988). None of the cited references teach a nucleic acid sequence. It is well-established law that a nucleic acid is not defined or described by its name (e.g., a cDNA encoding insulin), but "requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA." *Regents of the University of California v. Eli Lilly* and Co., 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Therefore, neither Katsurada (1997), Katsurada (1996) or Lal teach all of the elements of the present claims. Accordingly, Applicants request that the rejection of claim 1 under 35 U.S.C. §102(b) be withdrawn.

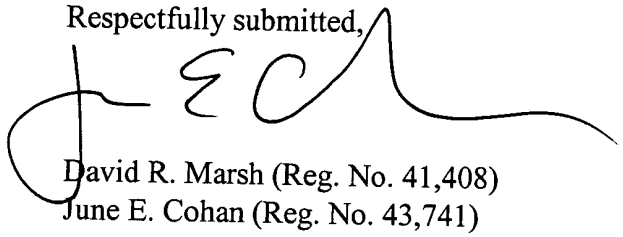
Claim 1 was rejected under 35 U.S.C. §102(a) as allegedly being anticipated by AAC27702 and AF061837. A rejection under 35 U.S.C. 102 (a) is only proper if, *inter alia*, an anticipatory printed publication describes the invention before an Applicants' date of invention. With respect to § 102(a), the AAC27702 and AF061837 references cited by the Examiner appear to have been published after Applicants' filing date. The Examiner assigned dates to the references under §102(a) as follows: AAC27702 (02-Oct-1998); and AF061837 (29-July-1998). For each of database entries AAC27702 and AF061837, the Examiner apparently relied on the date the sequence was submitted to the database, rather than the date it was available in a printed

publication or published. As such, Applicants respectfully request that the Examiner withdraw this rejection.

In view of the above, each of the presently pending claims in the application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested in withdraw the outstanding rejections of the claims and to pass this application to issues. The Examiner is invited to contact the undersigned at (202) 942-5071 with respect to any unresolved issues remaining in this application.

The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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MARKED UP CLAIMS

1. (Amended) A substantially purified nucleic acid molecule that encodes a maize or soybean phosphogluconate pathway enzyme [or fragment thereof], wherein said maize or soybean phosphogluconate pathway enzyme is selected from the group consisting of:

(a) glucose-6-phosphate-1-dehydrogenase[or fragment thereof];

(b) 6-phosphogluconate dehydrogenase[or fragment thereof];

[(c) putative 6-phosphogluconate dehydrogenase or fragment thereof;]

[(d)] (c) D-ribulose-5-phosphate-3-epimerase[or fragment thereof];

[(e)] (d) ribose-5-phosphate isomerase[or fragment thereof];

[(f) putative ribose-5-phosphate isomerase or fragment thereof;]

[(g)] (e) transketolase[or fragment thereof];

[(h) putative transketolase or fragment thereof;]

[(i)] (f) transaldolase[or fragment thereof]; and

[(j) putative transaldolase or fragment thereof;]

[(k)] (g) phosphoglucoisomerase[or fragment thereof];

wherein the substantially purified nucleic acid molecule comprises a nucleic acid sequence that hybridizes under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, 619 and the complements thereof.

2. (Amended) The substantially purified nucleic acid molecule according to claim 1, wherein said substantially purified nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting of [SEQ ID NO: 1 through SEQ ID NO: 699] SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619.

10. (Added) An isolated nucleic acid molecule comprising a sequence that hybridizes under conditions of 6.0 X sodium chloride/sodium citrate (SSC) at about 45°C, followed by a wash of 2.0 X SSC at 50°C to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, 619 and complements thereof.

11. (Added) The isolated nucleic acid molecule, according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619.

12. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 1.

13. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 4.

14. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 14.

15. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated

nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 27.

16. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 225.

17. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 298.

18. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 311.

19. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 356.

20. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 569.

21. (Added) The isolated nucleic acid molecule according to claim 10, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence of SEQ ID NO: 619.